K030845

MAY 22 2003

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
P.O. Box 50457
Indianapolis, IN 46250-0457

Contact Person: Jennifer Tribbett

Date Prepared: March 14, 2003

2) Device name

Proprietary name: CoaguChek™ PT•S Test for Prothrombin Time Self-Testing

Common name: Prothrombin time test

Classification name: Prothrombin time test

3) Predicate device

The Roche Diagnostics PT•S test strip and controls on the CoaguChek System for Patient Self-Testing are substantially equivalent to other products in commercial distribution intended for Patient Self-Testing. Most notably, the system is substantially equivalent to the currently marketed CoaguChek System for Prothrombin Time Self-Testing (K962571).

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4) Device Description

The CoaguChek PT•S Test is for quantitative prothrombin time testing in fresh capillary blood with the CoaguChek System by properly selected and suitably trained patients or their caregivers on the prescription or other order of the treating doctor.

Blood coagulation is one of the body's protective responses. Blood clots (thrombi) form as a direct response to vessel injury, preventing excessive loss of blood. Certain disease conditions require oral anticoagulants, sometimes known as blood thinners. Warfarin, sometimes known as Coumadin®, is a commonly used anticoagulant. Patients on warfarin must be carefully monitored to ensure the anticoagulant level is maintained in the therapeutic range. One method for monitoring the anticoagulant level is by using the one-stage Prothrombin Time (PT) Test. The PT•S test strip uses a modified version of this method.

The PT•S test strip, used as directed with the CoaguChek monitor, will accurately measure blood PT values. After placing a drop of fresh whole blood on the test strip, the blood is drawn into the reaction chamber and mixed with reagents that cause coagulation to begin. In the test strip, tiny iron particles are mixed with the sample. Alternating magnetic fields cause the iron particles to move within the sample. The endpoint is reached when the blood clot stops the iron particles from moving. The PT result is then displayed by the monitor.

5) Intended use

For quantitative prothrombin time testing in fresh capillary blood with the CoaguChek System by properly selected and suitably trained patients or their caregivers on the prescription or other order of the treating doctor.

6) Similarities to and differences from predicate device

Topic	CoaguChek System for Prothrombin Time Self-Testing (K962571)	CoaguChek System for Prothrombin Time Self-Testing with the PT•S Test Strip and Controls
Intended Use	For quantitative prothrombin time (PT) testing in fresh capillary blood with the CoaguChek System by properly selected and suitably trained patients or their caregivers on the prescription or other order of the treating doctor.	Same
Test Principle	After placing a drop of fresh capillary blood on the test strip, the blood drawn into the reaction chamber and mixed with reagents that cause coagulation to begin. In the test strip, tiny iron particles are mixed with the sample. Alternating magnetic fields cause the iron particles to move within the sample. The test is complete when the blood clot stops the iron particles from moving. The PT result is then displayed by the monitor.	Same
Reagents	Each test strip contains rabbit thromboplastin, stabilizers and preservatives	Each test strip contains human recombinant thromboplastin, stabilizers, a heparin neutralizing agent and preservatives
International Sensitivity Index	ISI is approximately 2	ISI is approximately 1
Storage and Stability	You may store strips at room temperature for up to 60 days, then refrigerate until the "Use By" date.	(Improved) You may store strips at room temperature for up to 90 days, then refrigerate until the "Use By" date.

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New System vs. Predicate System *-Continued-*

Topic	CoaguChek System for Prothrombin Time Self-Testing (K962571)	CoaguChek System for Prothrombin Time Self-Testing with the PT•S Test Strip and Controls
Storage and Stability	Remove one test strip foil pouch from the refrigerator. Allow the sealed pouch to set at room temperature for at least five minutes before opening for testing.	(Improved) A warm up period of 5 minutes is not necessary with the PT•S test strip.
Storage and Stability	Use the test strip within four minutes after opening the foil pouch.	(Improved) Use the test strip within ten minutes after opening the foil pouch
Quality Control Recommendation	Two levels of control should be tested upon receipt of each test strip carton and each day of use.	Same
Verified Clinical Range	0.6 - 8.0 INR	0.8 - 8.0 INR
Accuracy	N = 315 observations Slope = 0.973 Intercept = 0.05 Correlation Coefficient = 0.966	N = 84 observations Slope = 1.011 Intercept = -0.03 Correlation Coefficient = 0.978
Precision	**Patient Results** / **Professional Results** N 1070 / 40 Mean 3.81 / 3.78 SD 0.39 / 0.35 CV 10.31 / 9.30	**Patient Results** / **Professional Results** N 841 / 140 Mean 2.33 / 2.35 SD 0.15 / 0.14 CV 6.45 / 5.79

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Jennifer Tribbett
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

MAY 22 2003

Re: k030845
Trade/Device Name: CoaguChek™ PT•S Test for Prothrombin Time Self-Testing
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: II
Product Code: GJS
Dated: March 14, 2003
Received: March 17, 2003

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030845

Device Name: CoaguChek™ PT•S Test for Prothrombin Time Self-Testing

Indications for Use:

For quantitative prothrombin time testing in fresh capillary blood with the CoaguChek System by properly selected and suitably trained patients or their caregivers on the prescription or other order of the treating doctor.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030845

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)